

UKRG INITIATIVES

Radiopharmaceutical Quality Control Techniques: Theory and Practice

Stay tuned. Announcement expected imminently of a repeat of this 1½ day course offered previously in 2008.

New guidance documents

UKRG intends to issue two new guidance documents over the summer:

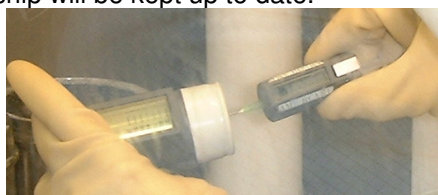
- Quality assurance of radiopharmaceuticals
- Safe dispensing and administration of radioactive medicinal products in nuclear medicine departments

Resheathing of needles

The Health and Safety Executive has proposed a blanket ban on the resheathing of needles in accordance with EU directive 2010/32/EU "Implementing the Framework Agreement on Prevention from Sharp Injuries in the Hospital and Healthcare Sector." This is due to concern about staff exposure to blood borne viruses from needlestick injuries. The situation is completely different in radiopharmacy where only sterile needles are used in production and resheathing of needles is essential, eg prior to using dose calibrator to measure activity in syringe.

As this is an EU directive, it cannot be changed before implementation. However, the "get out clause" may be that it applies "where the results of the risk assessment reveal a risk of injuries with a sharp and/or infection" (clause 6). Thus, local risk assessments may support exemption from this requirement. However, the use of low risk recapping devices (to the extent that such are available) is to be encouraged.

The UKRG is lobbying on this issue and the readership will be kept up to date.



MOLYBDENUM

Strategic report to Department of Health

The National Imaging Board commissioned ARSAC to prepare a report and recommendations on the medium term response to the molybdenum situation. That strategic report, which endeavours to ensure the stable supply of ^{99m}Tc labelled products to nuclear medicine, may have far reaching effects on the practice of radiopharmacy. The report appeared on the ARSAC website last December. www.arsac.org.uk

The Department of Health will be meeting in June to explore how it will address the recommendations contained in the report.

REGULATORY ISSUES

Recent MHRA inspections

Issues which have come up in recent inspections have included:

- *Sterile face masks* must be worn in Grade A and B areas.
- *The relationship between production and QA surrounding release*: It is imperative to ensure that both parties are aware of all the information required for release. The production pharmacist can perform batch release in accordance with the quality system, and the QA person needs to be confident that the system is robust. Personnel carrying out batch release must be qualified to do so.
- *Training records*: SOPs must be available, along with documented evidence that training on the SOPs has been carried out. Appropriate time must be allowed for validation.
- *Broth tests*: Every six months is the minimum allowed for an operator. The practice of carrying out broth tests every three months ensures the minimum number is achieved. Also operators must demonstrate competency in all manipulations, so any unusual or complex manipulations must be included in the broth test.

MEETING REPORTS

Becquerel Medal Symposium in honour of Professor Helmut Maecke

A symposium organised by Phil Blower and Steve Mather on behalf of the Royal Society of Chemistry Radiochemistry Group was held on 4 April in London to honour Helmut Maecke on his retirement from Basel, though he is continuing to work in Freiburg. There was a good attendance by the UK radiopharmacy community.

The symposium coincided with the IUPAC International Year of Chemistry and the centenary of the Nobel Prize in Chemistry to Marie Curie. The programme ended with a recital of piano music composed by Marie Curie's compatriot Frederic Chopin.

A full report can be found in a recent EANM Newsletter and at:

http://www.rsc.org/images/Becquerel%20Medal%20report_tcm18-201144.pdf

BNMS Annual Meeting, Brighton

This year BNMS was back in Brighton, and if it's Tuesday it must be radiopharmaceutical sciences day. While numbers were down this year, the select few were still treated to a full day of radiopharmacy presentations: four invited talks and seven proffered papers.

The invited presentations were:

- Nuclear imaging at the nanoscale, K Al-Jamal, King's College London
- 35 years in radiopharmacy: the view from the golf course, S Mather, Queen Mary University
- Practical aspects of using ^{68}Ga generators, J Ballinger, Guy's and St Thomas' Hospital
- $^{99\text{m}}\text{Mo}$ supply: today and tomorrow, D Lewis, AIPES

The proffered papers encompassed nanoparticles, ^{64}Cu labelled antibodies, measuring radionuclidic impurities in ^{18}F , GMP compliance in PET, ^{68}Ga generators and chelates, and modelling $^{99\text{m}}\text{Tc}$ generator yields and costs.

It should be noted that several of the prizes went to radiopharmacy papers presented in other sessions, including one on the oxygen sensitivity of hypoxia tracers (multimodality oral prize) and another on developing an imaging tool to monitor IgE therapy (joint 1st oral prize).

Most of the presentations are available on the BNMS website in the members' area.

WORKFORCE ISSUES

Modernising scientific careers

At last, perhaps, some joined up thinking. There seems to be some coordination between Modernising scientific careers and modernising pharmacy careers. There are three work streams: pre registration education and training; post registration career development; and workforce planning.

It is looking more and more that the formal route into the field will be a combined Clinical Pharmaceutical Sciences training programme (STP), encompassing radiopharmacy, aseptics, production, and quality assurance. It is possible that the current PTQA programme could be rejigged to fit STP, though presumably any college could tender to provide this training as has been done with medical physics. The STP will be structured as:

- Year 1: core knowledge including management and basic healthcare
- Year 2: specialty modules
- Year 3: higher training

If this were to follow the medical physics example, the training would be provided through supernumerary positions, which is something radiopharmacy has been pursuing for a number of years and would represent a great advance.

RESEARCH NEWS

Somatostatin peptides

The situation around availability and legality of somatostatin peptides for imaging and therapy is as murky as ever.

Much work has been carried out over a number of years with ^{90}Y -DOTATOC and ^{177}Lu -DOTATATE. A couple of years ago Molecular Insight bought the rights to ^{90}Y -DOTATOC and began enforcing its patent. This meant that DOTATOC could not be sold to radiopharmacies which had been using it for years for imaging or therapy. The European trials were to be coordinated by Biomedica Life Sciences, who offered DOTATOC kits for compassionate use at an exorbitant price.

However, late last year Molecular Insight filed for bankruptcy protection. There are links to the court documents from their website and they make interesting and at times entertaining reading. One of the accusations is that Bachem, the supplier of DOTATOC chemical, dumped stock onto the

market just before the patent enforcement took effect. Molecular Insight has found new investors and has recently emerged from bankruptcy protection with new vigour to pursue licensing of ⁹⁰Y-DOTATOC.

DOTATATE is also patented but the patent was not being enforced. Thus, GMP grade DOTATATE was available from ABX and possibly other suppliers, and DOTATATE kits from Polatom for ⁹⁰Y or ¹⁷⁷Lu labelling (but not suitable for ⁶⁸Ga). However, recently there have been press releases and a posting on VirRad that a German company called OctreoPharm is pursuing licensing of ⁶⁸Ga-DOTATATE (I think) as SOMscan. This may mean that DOTATATE kits will no longer be available.

The UKRG is monitoring the situation and trying to ensure that there is a source of DOTATATE and/or DOTATOC kits until fully licensed products are available on the market.

Molecular radiotherapy in the UK

The British Institute of Radiology has issued a report entitled "Molecular radiotherapy in the UK: Current status and recommendations for further investigation." The report identifies lack of specialist radiopharmacy support as one of the limitations to more widespread use of these therapies. The report can be purchased from BIR. www.bir.org.uk

INDUSTRY NEWS

Mediam re-introduces Hepatate

After a lengthy absence, Hepatate (tin colloid) has returned to the UK market. GE transferred its licence for Hepatate to Mediam. As Mediam does not currently have a UK agent, products must be ordered through Durbin. Mediam also supplies Cholediam (mebrofenin), which it took over from CIS, and is working on Stannous Agent, also from GE.

Mediam has asked me to distribute the following statement:

"As you may know, it is necessary to comply with all European and National regulations to market a pharmaceutical product. To do this, new dossiers (called variations) have to be submitted to the respective agency. Thus, 3 variations have been required for Hepatate. In light of this review, I would like to stress that Cholediam and Hepatate required significant investment for a small company like Mediam. Apart from the regulatory costs (new GMP product, new dossier, etc.), the active ingredient of cholediam is very expensive. Additionally, the size of the batches of Hepatate and Cholediam are small which means a

discrepancy between fixed costs and the size. We do hope these products will meet your clinical and imaging expectations." Franck Rouaix
contact@mediam-pharma.com

New cardiac stress agent from GE

GE will be the UK distributor of regadenoson (Rapiscan), the coronary vasodilator used for pharmacological stress in myocardial perfusion studies. Since its launch in the USA three years ago it has become the most widely used stress agent due to its simplicity of use (bolus injection, no weight adjustment) and safety profile. Information is available from your GE rep.

Product shortages at GE

GE has announced that medronate will be off the market for at least a year due to "lack of availability of one of the raw materials used in the manufacture of this product." There is one other UK licensed supplier of medronate (although it has been in short supply on occasion), and alternative bisphosphonates are available from two other companies.

IBA

Last September IBA held an open house at their new facility in Saclay. Some of you were able to attend. The presentations from that meeting are now available. Contact your IBA rep for a password to access them.

Covidien moves ¹²³I production site

Covidien has moved its ¹²³I production to a new cyclotron in Petten. It is anticipated that reliability of production will improve greatly.

Agilent is new supplier of iTLC-SG/SA

Varian brought iTLC-SG and -SA thin layer chromatography media back onto the market last year. Varian products are now sold via Agilent.

<http://www.chem.agilent.com/en-US/products/columns-supplies/thinlayerchromatography/itlc-sg/Pages/default.aspx>

Contact: James Stratta, 07714 071127

Monitors show radionuclide Bq/cm² measurements instantly

Newly available from LabLogic Systems are radiation monitors offering an exceptional range of features tailored to the needs of nuclear medicine. In addition to giving a standard reading in counts-per-second (cps) Tracerco monitors are calibrated against 14 other radionuclides as standard, showing Bq/cm² on the digital display at the press of a button without any need for calculations by the user. A further nine calibrations can be added, as required. Robustly made in the UK, the monitors can be used with a one-handed sweeping action or

with a probe for reaching into less accessible areas, such as fume cabinets. The standard T401 GM-based model is complemented by three others: the T402 dose rate meter (60KeV - 1.25MeV, with peak dose feature and cumulative dose measurement); the T403 with 10m of cable and a 10m-long extendable pole; and the new T406 for monitoring X-rays from 17KeV to 1.25MeV. www.lablogic.com

New radio HPLC detector pleases PET oncologists

LabLogic's new Flow-RAM gamma radio HPLC detector for PET and SPECT is already attracting positive comments from its first UK customer - Imperial College's Hammersmith Hospital Campus in London. Dr Graham Smith of the Faculty of Medicine's Comprehensive Cancer Imaging Centre, where the detector is used for quality checks of radio-pharmaceuticals, says: "The Flow-RAM hardware is an ergonomic improvement on the setup we had previously, and it integrates seamlessly into Laura radiochromatography software, generating data of comparable quality. Installation was carried out with the technical expertise that we have come to expect from the company, reinforced by excellent after-sales support." With the Flow-RAM, Hammersmith anticipates the high degree of reliability it has already experienced with LabLogic's Gamma-RAM radio-HPLC detector for soft and intermediate gamma emitters, which has not malfunctioned or shown signs of degradation in sensitivity in more than three years of use.

Flow-RAM is available in different configurations whereby either one or two detectors can be connected to the system at any one time. The two-detector configuration accepts two detectors - different or the same - that work simultaneously yet independently of one another. This creates a 'two in one' instrument, giving exceptional flexibility, hence saving space and money. The user can lock down features such as the high voltage, upper and lower level discriminators to prevent unauthorised adjustments to specified radionuclide operating parameters, ensuring consistent GLP/GMP compliance. Power supply, instrument control and data collection is via a single USB connection. In addition, for those wishing to use the detector with their existing chromatography system, the Flow-RAM offers stand-alone control through a pocket digital assistant over a Bluetooth wireless link.

New radio-TLC scanner for PET and SPECT saves space (and cash)

LabLogic's new Scan-RAM radio-TLC scanner detector for PET and SPECT nuclear medicine imaging has been designed so that the detector and collimator are moved rather than the bed itself, so no additional operational space is required. Scan time is completely user-definable and

generally takes between one and two minutes, depending on the level of radioactivity. The radio-TLC strips are supported by TLC support removable, easily cleaned beds that accommodate different sizes, lowering the user's finger exposure and preventing contamination of the Scan-RAM.

Scan-RAM can be configured with either one or two detectors connected to the system at any one time. The two-detector configuration is particularly useful for labs that need a radio-TLC scanner and a radio-HPLC detector in the same system but have limited space (and money). To ensure the integrity of GLP/GMP compliance, features such as the high voltage, upper and lower level discriminators can be locked down to prevent unauthorised adjustments to specified operating parameters. Power supply, instrument control and data collection is via a single USB connection.

Scan-RAM is controlled by LabLogic's Laura radiochromatography software. Another option - for those wishing to use the Scan-RAM with their existing chromatography system - is stand-alone control through a pocket digital assistant over a Bluetooth wireless link. To optimise Scan-RAM's performance, LabLogic offers an extensive range of detectors (NaI/PMT, plastic scintillator/PMT, well type NaI/PMT, pin diode, etc) - and advise on the most suitable type for every application.

New chromatography data system is PET-specific

LabLogic has introduced a version of its tried and tested Laura chromatography data system specifically for PET applications. The aptly-named 'Laura for PET' is a single system that can control and collect data generated by all standard methods - gas, thin-layer and high pressure chromatography and multi-channel analysis. Data is collected digitally to ensure accuracy and is also easy to extract for QC acceptance purposes, and half-life can be corrected on-line - a feature unique to 'Laura for PET'. Audit trails can be configured to suit individual requirements; results can be calibrated for quantitative data analysis; and methods, calibrations and reports can all be locked against modification to ensure consistency of operation. "Introducing 'Laura for PET' reduces the number of data systems that have to be learned to just one, so disruption to the PET lab's production process is kept to an absolute minimum," says Keith Hall, LabLogic's Laura product manager. "Users also have the reassurance of knowing that it is based on a reliable product designed specifically for working with radio nuclides as well as "cold" techniques that has successfully evolved in response to chromatographers' changing needs for more than 20 years."

UPCOMING MEETINGS

1st World Congress on Ga-68 and Peptide Receptor Radionuclide Therapy (PRRNT)

23-26 June, Bad Berka, Germany
www.1stworldcongress-ga-68.de

19th International Symposium on Radiopharmaceutical Sciences

28 Aug – 2 Sep, Amsterdam.
www.isrs2011.org

7th International Conference on Isotopes

4-8 September, Moscow.
www.isotop.ru/en/events/description-event/

European Nuclear Medicine Congress

15-19 October, Birmingham.
www.eanm.org

From Dosimetry to Biological Effect: Radiobiology as a Guide to Clinical Practice in Nuclear Medicine

5-8 Nov, Sorrento, Italy.
www.nuclearmedicinediscovery.org

7th National Cancer Research Institute Cancer Conference

6-9 Nov, Liverpool.
www.ncri.org.uk/ncriconference

4th International Conference on Radiopharmaceutical Therapy (ICRT-2011)

World Association of Radiopharmaceutical and Molecular Therapy (WARMTH), 28 Nov – 2 Dec, Ho Chi Minh City, Vietnam. Abstract deadline: 27 July. www.icrt-2011.warmth.org

Chemistry for Imaging SINAPSE Spirit
6 Dec, Glasgow. Abstract deadline: 16 Sep.
www.sinapse.ac.uk

16th European Symposium on Radiopharmacy and Radiopharmaceuticals

26-29 Apr 2012, Nantes, France. Abstract deadline: 5 Dec.
<http://esrr12.eanm.org>

AS TIME GOES BY

I don't know if there's something in the water or what, but we have three recent or imminent retirements to acknowledge.

Steve Mather, noted for many things including being a previous editor of this Newsletter, needs no introduction to this readership, nor to anyone in the field of radiopharmacy worldwide, where the list of countries he has visited is longer than the ones he has not. As Steve told the audience at BNMS, he is not spending all his time on the golf course, but is wrestling with a recalcitrant PET synthesiser. He is this year's recipient of the BNMS Norman Veall Medal for his contributions to the science of nuclear medicine.

Jenny Wooten was manager of the Covidien radiopharmacy located at University College London Hospital, having taken over several years ago from Dominic Lui. She will be replaced by Mark Moran.

Barbara Wensworth leaves Bradford Royal Infirmary and was also heavily involved in teaching. Her last contribution to the UKRG Newsletter was two issues ago when she encouraged radiopharm techs to get on the GPhC register with all due haste. She is famous for wearing sandals even in January.

Jenny and Steve were feted at a dinner in London in April, and Barbara will be given a grand send off at a dinner in Birmingham in July. Best wishes to all!

www.ukrg.org.uk

Editor: Jim Ballinger
Department of Nuclear Medicine
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond, London, UK, SE1 9RT
Phone: 020 7188 5521; Fax: 020 7188 4094
E-mail: jim.ballinger@kcl.ac.uk

Issue 2011 Q2 Published 22 June 2011

This and previous issues of the Newsletter are available from the UKRG web site and are posted in the library section at www.VirRad.org